**IN THE HIGH COURT OF JUDICATURE AT BOMBAY**
**O.O.C.J.**
**WRIT PETITION NO. 2907 OF 2005**

1. Dr. Narendra Omprakash Bansal,
Adult, Occ. Govt. Service,
as Professor & Head of the
Department of Cardiology,
Grand Medical College,
J.J. Group of Hospitals,
Mumbai 400 008 and residing
at 5/30, J.J. Hospitals,
Mumbai 400 008.

2. Dr. Satish Vasant Vaidya,
Adult, Occ. Govt. Service,
Hon. Professor of Cardiology,
and Unit Head 2 at Grant
Medical College, J.J. Group
of Hospital, Mumbai 400 008
and residing at "Niwara",
Ramganesh Gadkari Path,
Thane 400 602. ... Petitioners

Versus

1. The State of Maharashtra,
through the Principal Secretary,
Medical Education, Mantralaya,
Mumbai 400 032.

2. The Director, Medical
Education & Research, Mumbai.

3. The Dean, Grant Medical
College and J.J. Group of
Hospitals, Mumbai 400 008. ... Respondents

Dr. Virendra V. Tulzapurkar, Sr. Counsel with Mr. R.D. Soni i/by Ram & Co. for Petitioner.

Mr. R.M. Sawant, Govt. Pleader for R. Nos. 1 to 3.

Mr. S.K. Talsania, Sr. Counsel with Mr. Amjad Sayed with Mr. L.M. Acharya for R. No. 4.

**CORAM : F.I. REBELLO &**

**DR.D.Y.CHANDRACHUD,JJ.**
**DATED : FEBRUARY 27, 2006**

Oral Judgment (Per F.I. Rebello,J.):

. The Petitioner No. 1 was holding the post as Head of the Department, Professor of Cardiology in the Grant Medical College and Sir J.J. Group of Hospitals, Mumbai. The Petitioner is working as Head of the Department since August, 2002.

2. The Petitioner No. 2 holds a degree of M.D. Medicines, D.M. Cardiology from Mumbai University and is working as Hon. Professor of Cardiology and Unit head 2 at Grant Medical College and Sir J.J. Hospital, Mumbai. Both the petitioners as of today are under suspension. The Petitioner No. 1 by order dated 13.7.2004 and Petitioner No. 2 by order dated 30.8.2005.

3. Petitioner No. 1 had challenged his order of suspension before M.A.T. by filing O.A. No. 637 of 2005. That O.A. was disposed of by order and judgement dated 8.9.2005 and the Petitioner No. 1 was

directed to approach the Government by way of Appeal/representation under Section 17 of the Maharashtra Civil Services (Discipline & Appeal) Rules. A direction was issued that if the Petitioner makes a representation, the same will be disposed of within two months. The Petitioners made representation which representations were rejected and the same was communicated to the Petitioners by letter dated 8.11.2005. It is against this order that the Petitioners have filed the present petition. Both the Petitioners have not approached M.A.T. after rejection of the representation but have chosen instead to directly file Writ Petition before this court.

. One of the challenges raised by the Petitioners is to the constitution of the Committee appointed by the State Government. A High Powered Committee headed by a retired Judge of this Court, has been appointed and one of the terms of reference is whether the Petitioners or any other doctors of JJ Hospital violated ethical code and/or whether the Petitioners used drug eluting stents for trial without following the procedure and whether the Petitioners committed the offence and if yes, what

action should be taken against them.

4. In the prayer Clause, Petitioners have sought change of constitution of the committee by excluding (i) Mr. Ramesh Kumar, FDA Commissioner (ii) Dr. Anand Dongre, Forensic Medicine Professor, (iii) Dr. Kirti Punamiya, Cardiologist from Bombay Hospital and (iv) Dr. Vijay Bang, Cardiology Professor from J.J. Hosptial from the said committee. The grievance of the Petitioners against these members is that Dr. Vijay Bang is an interested person being junior and is now acting Head of the department of Cardiology subsequent to the suspension of the Petitioner No.1. Dr. Kirti Punamiya is much junior to the Petitioner No.1. Mr. Ramesh Kumar has filed an affidavit to contend all through out against the opinion of the Drug Controller of India that the Drug Eluting Stent is a medicine and needed CE/FDA certification. The said stand taken by Ramesh Kumar has been proved to be wrong. The Respondent State was asked whether it was possible to make changes in the constitution of the committee. The learned Sr. Counsel for the State has placed on record a letter written by the Deputy Secretary, Government of

Maharashtra to the Asst. Government Pleader dated 24.2.2006. Dr. Vijay Bang and Dr. Poonamiya have been replaced by Dr. Susheel Munshi, Ex-Hon. Professor (Cardiology), KEM Hospital presently working as Cardiologist in Jaslok Hospital and Dr. Satyawan Sharma, Ex. Hon Professor (Cardiology), Nair Hospital, Mumbai presently working as Cardiologist in Bombay Hospital. In place of Mr. Ramesh Kumar, Commissioner, F.D.A. the Government has proposed the name of Mr. A.T. Vatkar, Senior Joint Commissioner, F.D.A. In our opinion, this would meet the challenges raised by the Petitioner for the constitution of the committee. The State Government is therefore, directed to issue a notification substituting the three members against whom objections were raised and in respect of whom the State Government has proposed new names. In so far objection against Dr. Anand Dongre is concerned, we find he is a professor of Forensic Medicines and we find no objection to his continuing on the committee. The relief sought for in prayer Clause (a) is accordingly disposed of.

5. The issue then arises is whether suspension of the

Petitioners should be interfered with. It is the case of the Petitioner No.1 that Petitioner had already approached the tribunal which had directed the applicant before it to make representation to the State Government. A representation was made. However, the representation has been rejected and it is in these circumstances, the Petitioners have moved the court contending there would be no point in their moving M.A.T. It is pointed out that the Petitioners were suspended on the ground that the Petitioners had used the drug eluting stents for trial and without following the procedure.

. The case of the Petitioner No. 1 is that till date he has performed about 80,000 angioplasties and about 30,000 angiographs in the last about 15 years. The Petitioner has 70 Research publications to his credit and has till date organized about 8 to 10 conferences successfully.

. Petitioner No. 2 is working as Hon. Professor of Cardiology and Unit Head 2 at the Grant Medical College and J.J. Hospitals, Mumbai. The Petitioner No. 2 has

also been active in the field of angioplasty and has till date performed about 20,000 coronary and non-coronary angiographies, 2000 procedures including coronary angioplastics and non-coronary interventions like valvuloplastics as well as permanent pacemaker implantations. The Petitioner No. 2 has delivered more than 250 lectures at various national and international conferences, symposia and seminars and has more than 50 publications in national and international journals to his credit.

6. It is pointed out that consequent to the development in the field of cardiology, open heart surgery, cardiologists are now using drug eluting stents which due to the element of medicines attached to it, reduces the risk of recurrence of ailment. The cost of the treatment in private hospitals is in the range of Rs.2 lacs depending on the number of stents required for the particular patient. Whereas the said treatment is given in the Government hospital at the average cost of Rs.60,00/- per patient. The most prominent and widely used stents in India are by the manufacturers like Johnson and Johnson, Boston

Scientific, Vasculir Concepts, Sahaj Anand, Shruti Medi Sciences etc. Out of this only Sahaj Anand and Vascular Concepts are indigenous and other three are imported. The cost of the stents are then set out. It is pointed out that the stents or drug coated stents are neither covered nor fell within the schedule of Drugs and Cosmetics Act. The stents were available in India as any other medicinal products and that stents which are imported are permitted to enter the country officially through regular import procedure. It is pointed out further that the only Johnson and Johnson and Boston Scientific stents are USA FDA approved which are branded items whose cost is exorbitant and unaffordable for the poor people of India. However, the stent of Occam which is the subject matter of this petition is cost effective and less than the half price with that of the branded items with the same result and quality which is proved by the regular feedback of patients on which the said stents are used over years. The Petitioners have been using the stents manufactured by several companies over the years including that of the Occam which costs about Rs.50,000/- and which has been used in about 89 cases in the Petitioner’s department out of which some cases are of other doctors

from the same unit. The Petitioners state that it is pertinent to note that regular follow up and check up of 89 patients have been made in the said department and there is not a single complaint from any of the patients who are perfectly hail and healthy and without any complication after the said stent was used and there is no fatality or complication relating to the use of the said stent till date. It is pointed out that the Medical Drug Controller of India has in fact certified that the medicated stent was not an item falling within the ambit of the Act nor was it part of the schedule. The question therefore, of there being any violation of the Drugs and Cosmetics Act or any necessity of permission from Drugs Controller of India or FDA as regards the aforesaid Occam manufactured stents did not arise at all. It is further pointed out that the stents manufactured by Occam are being used by about 64 prominent doctors and hospitals including private hospitals. A list is annexed at Exh. C. We may only point out that the list includes doctors from Jaslok Hospital and Research Centre, Mumbai, Lilavati Hosptial, JJ Hospital, P.D. Hinduja Hospital, Mumbai. Various other doctors including of Safdarjang Hosptial, New Delhi, St. John Hospital, Bangalore and others are

using the said stent as per the exhibit.

7. It is pointed out that the issue regarding status of the Drug Eluting Stents manufactured by Occam, Netherlands under the brand name "Axxion" came up for consideration before this Hon’ble Court in Writ Petition No. 2104 of 2005. The Petitioners state that a categorical statement was made on affidavit by the Secretary, Medical Education and also by the Drug Controller General of India that the Drug Eluting Stents was not regulated nor did it come within the purview of the Drug and Cosmetic Act. The Government of India has thereafter, issued a notification including the said device under the Drugs and Cosmetics Act and now has been incorporated in the Schedule as a device under Section 3(b)(iv) of the Drug and Cosmetic Act under the name of "Sterile Devices". The Government of India has now issued a notification on 6th October, 2005 listing the stent as a drug. In other words, it is from 6th October, 2005 that the stents including drug eluting stents have been notified as drugs.

. The Petitioners have also placed on record the certificate issued by EC Design Examination Certificate to Axxion Occam Stent Delivery System. It is issued on 11.7.2002 and reissued on 25th September, 2003. Another certificate has been issued on 11.7.2005 which expires on 10.7.2008. This would indicate that Occam stents which are known as Axxion has EC design examination certificate as also CE certificate. It is the case of the Petitioners therefore, that there was no material whatsoever to suspend the Petitioners and consequently the action of the respondents of continuing suspension is arbitrary and or disclose total non application of mind.

8. On behalf of the respondent State, Mr. Govind Rankhambe, the Deputy Secretary, Medical Education & Drugs Department, Mantralaya, Mumbai has filed an affidavit. It is contended that the Petitioner ought to have approached the tribunal which they have not done. The Petition on that count alone should be dismissed. The Petitioners have been suspended pending the departmental enquiry. The committee has been constituted and appointed by the Government in

compliance with the assurance given by the Hon'ble Minister on the floor of the Legislative Assembly for holding a detailed enquiry in the matter of use of drug eluting stents in the State of Maharashtra and specially their user in Government run hospitals. The findings given and conclusions drawn by the committee would be recommendatory in nature and it is not a departmental enquiry. The individual conduct of the Petitioner would not be investigated at all. The report of the committee after it is submitted may be relied upon by the Government in the departmental enquiry against the Petitioners as an additional piece of evidence in support of the charges framed against the Petitioners and that no action will be taken against the Petitioner solely based on the report of the committee. The order of suspension is pointed out was passed after preliminary enquiry and considering the clarifications given by the Petitioners. A report was submitted by Dr. Nagrale and is based on this report that the Government came to the conclusion that the Disciplinary proceedings be initiated.

. It is then pointed out that in so far as Petitioner

No. 1 is concerned, the chargesheet has been framed by the order dated 17.11.2005 and served on the Petitioner No. 1 as per rules. In case of Petitioner No. 2 charegsheet has also been submitted to the concerned authority for its approval and as soon as the approval is received, chargesheet will be served on the Petitioner No. 2 and further steps will be taken.

. It is then pointed out that the Petitioner No. 1 managed to cause the removal of the main registers from the cardilogy department by giving instructions to his juniors i.e. Dr. Shantanu Deshpande and Narsingh Pai. These registers pertain to the types of stents used at J.J. Hosptial by the actual operators. It may be pointed out that the Counsel for the State was asked whether the registers are now in the possession of State to which the learned counsel fairly submits that they are in their possession. It is set out that the Respondents have a genuine apprehension that if the Petitioners are allowed to resume their duties the documentary evidence would be tampered and since Petitioner No. 1 was the Head of the Department, his juniors and other staff who are witnesses in the

Departmental Enquiry would hesitate to depose against the Petitioners.

. It is also set out that the respondents have in their possession documentary evidence to show that Axion stent was not even sold in the country of its origin since the matter was under investigation. It is also pointed out that many of the stents did not have approvals in the country of origin and or international quality control authentication like USA, FDA or CE certification and that the Commissioner (FDA) Maharashtra has permitted sale and use of drug eluting stents which have international quality control authentication like USA, FDA or CE Certification. It is pointed out that the stents was accorded CE certification by the International agencies only on 11.7.2005 after the said stent was used on several patients by the Petitioners. It is pointed out that the drug eluting stents manufactured by OCCAM was used for clinical tests in J.J. Hospital, Mumbai. It is pointed out that the respondents have documentary evidence to show that the Petitioners were using the said stents on human subjects for and on behalf of the

said outsider manufacturer for research purpose and sending research reports of the said manufacturer through the marketing agency M/s. Shruti Mediscience Pvt. Ltd. It is further pointed out that the Petitioners have used these stents on as many as 89 patients without their express consent and without getting permission from the Ethical Committee of J.J. Hospital. In other words, the respondents contend that this was a new drug and was being used on an experimental basis.

. It is also pointed out that the Petitioners have been recovering illegal gratifications from the patients and giving bills of a lesser amounts. Reference is made to the case of Mrs. Sudha Madavi, who was operated for angioplasty on 6.10.2004. She was asked to pay Rs.2,25,000/- by Petitioner No. 1 and receipt was given only for Rs.1,20,000/-. Mrs. Sudha has filed a complaint on 26.7.2005. It may be mentioned that in the chargesheet, a charge to that effect has been included. The learned counsel for the State was asked whether any statement was recorded of Mrs. Sudha, before the charge was framed. The learned

counsel points out that as on the date of the argument, no statement had been recorded.

9. For the view to be taken, it is not necessary for us to record any finding of fact. From the material on record, it is clear that the drug eluting stents were not notified as drugs till the Government of India issued notification on 6.10.2005. There was no control earlier on drug eluting stents. It is apparent from the documents on record and which documents have not been disputed that CE certificate was issued to OCCAM International on 11.6.2002 and reissued on 25.9.2003. The EC design certificate to Axion has been issued on 11.7.2005 and which expires on 10.7.2008. In the affidavit of Govind Rankhambe which we have noted earlier, it is set out that the drug controller of Maharashtra has permitted use of medical having CE certification vide its notification on 6.6.2005. This order could have been issued if the drug eluting stents were included under Section 3 of the Drugs and Cosmetics Act, 1940 which has been done for the first time on 6th October, 2005. In other words, the notification of drug eluting stents as drug has been

done as on 6.10.2005. There is prima facie nothing on record to show that clinical trials have been done by the Petitioner No. 1 of the Axion Drug eluting stents. What is annexed by the respondent is a paper prepared by Petitioner No. 1 on studies conducted by him on the patients who had used Occam Axion drug eluting stents. As we have noted earlier, both the Petitioners by themselves have been presenting papers and have participated in seminars and Conferences. The paper by itself prima facie, cannot result in arriving at the conclusion that the drug eluting stents were being used on a trial basis. The further fact as may be noted is that respondents have not denied that particular stent was being used by Doctors in leading hospitals in this city as also in the Safdarjang Hospital, New Delhi.

10. When the Petitioner No. 1 had addressed representation to the Reviewing Authority, the Reviewing Authority must consider all material available and has to base its opinion on the material and then arrive at a conclusion as to whether the continued suspension of the Petitioner is required. In the instant case, reply filed on behalf of the respondent for continuation of suspension is that the

documents were missing. These documents and records are now in the possession of respondent. That by itself prima facie can be no ground for continuing suspension. It is then pointed out that the Petitioner No.1 being Head of Department, his junior members would be reluctant to depose against their seniors. The charges, prima facie are not of such a nature that juniors would be required to depose as there is no denial by the Petitioners that the drug eluting stents had been used. The only question is whether these stents can be used and further whether in fact these drugs have been used to conduct clinical trial by the Petitioners. We have already referred to CE certificate obtained for the drug. In so far as complaint of Mrs. Sudha Madavi, no statement of the said person has been recorded. The Petitioners are highly qualified Doctors. Their suspension is to deny their services to patient in need of the same. This aspect must be borne in mind by the Reviewing Authority.

. As noted earlier, we do not propose to interfere with the order of suspension. It will be open to the Petitioners however, to make an application for review

of the order of suspension. Considering the considerable experience they have in the field and the number of years that they have put in the service and the nature of the charges, the Reviewing Authority to consider that material on record which has been brought to our attention by the Petitioners and which has been adverted to while passing the order. Respondents are directed to dispose of the representation made by the Petitioner within four weeks of receiving the same.

. With the above directions, Petition stands disposed of.

**(F.I. REBELLO,J.)**

**(DR. D.Y. CHANDRACHUD,J.)**